

9-9-85

## DATA EVALUATION RECORD

1. Chemical: Glyphosate
2. Test Material: Technical - 83%
3. Study Type: Ninety-six hour Lepomis macrochirus LC50
4. Study ID: McAllister, W.A., Forbis, A.D.(1978) Acute toxicity of technical glyphosate to bluegill sunfish (Lepomis macrochirus), Analytical Bio Chemistry Laboratories, Inc., Columbia, MO. Submitted by Monsanto Co., on July 14, 1978, for Registration No. 524-308, Accession No. 234395

5. Reviewed by: Dennis J. McLane  
Wildlife Biologist  
EEB/HED

Signature: *Dennis J. McLane*

Date: 9-9-85

6. Approved by: Raymond W. Matheny  
Supervisory Biologist  
EEB/HED

Signature: *Raymond W. Matheny*

Date: 9-9-85

7. Conclusion:

This study can be used for hazard assessment purposes. Also, it meets the guideline requirements. Using the toxicity categories of Brooks et al. (1973) the acute LC50 of 120 ppm mg/L would place technical glyphosate into the category of practically nontoxic.

8. Recommendation:

N/A

9. Background:

This study was submitted to RD on July 14, 1978, and reviewed on July 19, 1978, by D. Urban. The present review was prompted by the Registration Standard for Glyphosate.

10. Discussion of Individual Tests:

N/A

11. Materials and Methods: (excerpted from citation)

The procedure for static bioassay, as described in Standard Methods for Examination of Water and Wastewater; and Methods of Acute Toxicity Test with Fish, Macroinvertebrates, and Amphibians, were used in this experiment. The bluegill sunfish used in this test were obtained from Osage Catfisheries, Inc., in Osage Beach, Missouri. All test fish were held in culture tanks and observed for at least 14 days prior to testing. During this period, the fish received a standard commercial fish food (Rangen's No. 1 Fry) daily until 48 hours prior to testing, at which time feeding was discontinued. The bluegill sunfish used for this experiment had a mean weight of 0.96 gm and a mean length of 34.2 mm.

The static fish bioassay was conducted in 5-gallon glass vessels containing 15 liters of reconstituted water composed of the following compounds in the amounts stated per liter of deionized water:

48 mg  $\text{NaHCO}_3$   
30 mg  $\text{CaSO}_4$   
30 mg  $\text{MgSO}_4$   
2 mg KCl

These vessels were kept in a water bath at  $21^\circ\text{C}$  ( $\pm 1.0^\circ$ ). The test fish were acclimated and voided from food 48 hours prior to testing.

An initial range-finding experiment was conducted using 10 fish per concentration level. The range was found by beginning at 0.1 mg/L and increasing the amount of test material by a factor of 10 until a toxic level was found. Once this level had been determined, 5 concentrations of the test compound with 10 fish per concentration were selected for their respective bioassays.

12. Reported Results: (excerpted from the citation)

Table 1 presents the predicted  $\text{LC}_{50}$  values and 95 percent confidence intervals for Technical Glyphosate and the reference test against Antimycin A, a piscicide. Survival rates, concentration, and water quality data are presented in Table 2.

The dissolved oxygen concentration which stayed between 60 percent and 100 percent saturation was considered adequate for testing. The pH values for all concentrations remained consistent with the controls throughout the test and the ammonia concentrations were below the toxic limit.

Table 1

Acute Toxicity of Technical Glyphosate and a Reference Compound (Antimycin A) to Bluegill Sunfish\* (Lepomis macrochirus)

Compound	LC <sub>50</sub> in milligrams/liter (ppm)		
	24 hours	48 hours	96 hours
Technical Glyphosate	121 (82-178)**	120 (111-130)	120 (111-130)
Antimycin A	.00020 (.00015-.00027)	.00015 (.00012-.00020)	.00010 (.00009-.00012)

\* Bioassay as conducted at 21 °C (+ 1.0°), mean weight and length, 0.96 gm and 34.2 mm.

\*\* 95 percent confidence interval.

13. Study Author's Conclusions/QA Measures:

No information was provided for this category.

14. Reviewer's Discussion and Interpretation of the Study:

a. Test Procedures: The following items do not follow the guideline requirements:

1. The holding period was not reported.
2. The pretest fasting period was 48 rather than 96 hours.
3. Toxic symptoms were not reported or discussed.
4. The dose levels were not geometrically spaced.

b. Statistical Analysis: The Litchfield and Wilcoxon is the method used for deriving the LC<sub>50</sub>. This is a probit method which is not valid when there are less than two concentrations at which the percent dead is between 0 and 100. The attached printout from the EEB program indicates that the binomial method is acceptable. In either case the LC<sub>50</sub> of 110 ppm (binomial) or 120 ppm (probit) would be treated the same in a hazard assessment. Both would indicate a practically nontoxic material for bluegill.

- c. Discussion/Results: In this case, the test procedures which deviate from the guidelines would not be expected to significantly change the LC<sub>50</sub> value. Based on this, the study is acceptable for hazard assessment and meeting guidelines.
- d. Adequacy of Study:
1. Classification: Core for technical glyphosate.
  2. Rationale: Due to the low toxicity of this material the deviations in procedures would not be expected to change significantly.
  3. Repairability: N/A
15. Completion of One-Liner for Study:
- Completed July 26, 1985.
16. CBI Appendix:
- N/A

RECORD OF TELEPHONE CALL OR VISITOR			DATE	Time
INCOMING CALL <input type="checkbox"/>	OUTGOING CALL <input checked="" type="checkbox"/>	VISITOR <input type="checkbox"/>	5/29/85	1:34pm

NAME OF PERSON  
LYLE GINGERICIL

NAME & ADDRESS OF COMPANY MONSANTO COMPANY	COMPANY TEL. NO. (Include Area Code)
	223-6968
	REGISTRATION NO. OR FILE SYMBOL
DATE OF LATEST SUBMISSION	

BRIEF SUMMARY OF CONVERSATION

Mr. Gingericil returned my call inquiring as to the purity of the glyphosate technical used in the following three studies.

ACC. NO.	MRID NO.	AUTHOR(s)
234395	MCOGLY07	McALLISTER & FORBIS
097661	MCOGLY08	THOMPSON & McALLISTER
097759-C	00108172	McALLISTER & FORBIS

ACTION TAKEN

All three tested the 83% technical glyphosate.

RECORDED BY (Name) D. MCLANE	REFERRED TO (Name) 5
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MCLANE GLYPHOSATE BLUEGILL

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
180	10	10	100	.0976563
140	10	10	100	.0976563
120	5	5	100	3.125
100	10	0	0	.0976563

THE BINOMIAL TEST SHOWS THAT 100 AND 140 CAN BE  
USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT  
CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL  
ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 110.018

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE  
PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE  
NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

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VALIDATION SHEET

Page 1 of 2

CHEMICAL NAME: N-phosphonomethylglycine

FORMULATION: Technical Glyphosate

TEST TYPE: Fish Acute 96-hour LC<sub>50</sub> - Bluegill sunfish

TEST ID NUMBER: ES-F1

CITATION: Accession No. 234395; Prepared by W. A. McAllister and A. D. Forbis, Analytical Biochemical Laboratories, Inc., P. O. Box 1097, 7200 East ABC Lane, Columbia, Missouri 65201; Dated: March 31, 1978; Title: Acute Toxicity of Technical Glyphosate to Bluegill Sunfish (*Lepomis macrochirus*). Submitted by: Monsanto Company, St. Louis, Missouri 63166.

VALIDATION CATEGORY: Core

- RESULTS: (1) The fish acute LC<sub>50</sub> of technical glyphosate in the Bluegill sunfish is 120 ppm (111 - 130, 95% C.I.).
- (2) The fish acute LC<sub>50</sub> of the positive control, Antimycin A in the Bluegill sunfish is 0.00010 ppm (0.00009 - 0.00012, 95% C.I.).

VALIDATION CATEGORY RATIONALE: N/A

CATEGORY REPAIRABILITY/RATIONALE: N/A

ADDITIONAL INFORMATION:

Procedures: (1) ASTM 1975, and (2) Methods of Acute Toxicity Test with Fish, Macroinvertebrates, and Amphibious (Stephan, 1975).

Water: Soft Re-constituted (after Stephan, 1975, p. 17).

Water Temperature: 21 ± 1.0°C.

Fish: Bluegill sunfish with a mean weight equal to 0.96 g, and a mean length of 34.2 mm. Fish

were fasted for 48 hours prior to testing.

Bioassay Vessel: 5 gallon glass vessel containing 15  
liters of soft re-constituted water.

Reviewer Comment:

The submitted data was analysed by a pre-  
programmed Spearman-Kärber method using the  
TI-59. The results follow:

10.	\$TRM
119.33	LC50
111.62	LOCL
127.56	UPCL

VALIDATOR: D. J. Urban

DATE: 7/19/78



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